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EXAMINING THE UNITED STATES PREVENTIVE SERVICES TASK FORCE
WEDNESDAY, NOVEMBER 30, 2016
House of Representatives,
Subcommittee on Health,
Committee on Energy and Commerce,
Washington, D.C.

The subcommittee met, pursuant to call, at 11:02 a.m., in Room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Shimkus, Murphy, Burgess, Blackburn, Lance, Bilirakis, Long, Bucshon, Brooks, Collins, and Pitts.

Staff Present: Rebecca Card, Assistant Press Secretary; Jay Gulshen, Legislative Clerk, Health; Dan Schneider, Press Secretary; Adrianna Simonelli, Professional Staff Member, Health; Heidi Stirrup, Health Policy Coordinator; Dylan Vorbach, Deputy Press Secretary; Waverly Gordon, Minority Professional Staff Member; Samantha Satchell, Minority Policy Analyst; and Arielle Woronoff, Minority Health Counsel.

Mr. <u>Pitts.</u> The subcommittee will come to order. I might note that the Democratic members of the subcommittee are still at their caucus leadership elections. They will come as soon as they finish that.

The chairman will recognize himself for an opening statement.

Today's hearing will be taking a close look at the United States

Preventive Services Task Force created in 1984 as an independent

volunteer panel of 16 national experts in prevention, primary care,

and evidence-based medicine and tasked with making recommendations

about clinical preventive services which could work to improve the

health of all Americans.

The Affordable Care Act required the Task Force to issue annual reports to Congress, to include information on gaps in the evidence-based research related to clinical preventive services, and recommend areas that need further examination through targeted research. The Affordable Care Act also tied some of the Task Force recommendations directly to reimbursement requirements for private insurance.

Recommendations do not consider cost-effectiveness and are based solely upon evidence of medical benefit to the patient, no matter how expensive it is. The Task Force independently evaluates the medical evidence on clinical preventive services to inform healthcare professionals, healthcare systems, and the American people to make careful decisions about their health and health care. It is believed that by identifying evidence gaps and highlighting them as priority

areas for research will inspire public and private researchers to collaborate, target their efforts to generate new knowledge, and address important health priorities.

However, experience has shown that a number of the Task Force recommendations have the effect of limiting access to preventive care. For example, one recommendation was against screening for prostate cancer in healthy men with a prostate-specific antigen blood test. Another recommendation was against routine annual mammogram screenings for women age 40 to 49. Such recommendations contradict clinical guidelines based on medical literature and experts in the field. The concerns are that these recommendations could undermine new models of care delivery.

Our colleague, vice chair of the full committee, Representative Marsha Blackburn, has a legislative discussion draft entitled, quote, "USPSTF Transparency and Accountability Act of 2016," unquote, which would require specialists and subspecialists to be involved in reviewing the preventive services examined by the Task Force. The legislation would allow a wide range of patient groups, providers, and Federal agencies to be involved in the important review process of preventive services. Furthermore, any evidence reports and recommendations would be available for public comment. Transparency is further enhanced by establishing a preventive services stakeholders board to provide feedback on Task Force activities.

We have before our committee today some of the very stakeholders who can answer our questions surrounding the proposed legislation. So

I look forward to hearing more about the work conducted by the Task Force, how it might be improved with passage of this legislation, and recognize --

Anyone seeking time? Dr. Burgess.

Mr. Burgess. Thank you, Mr. Chairman.

So people familiar with this subcommittee know I never come without my copy of the Affordable Care Act, and this morning we are concerned about section 2713, which by Federal statute linked preventive service coverage requirements to the recommendations of the federally appointed United States Preventive Services Task Force.

Interestingly, this entity is not subject to the Federal Advisory Committee Act or the Administrative Procedures Act, providing the public with little opportunity for accountability and transparency and no review and comment period. So we have seen from past experiences with the prostate-specific antigen, the PSA test for prostate cancer, from mammograms for breast cancer, the Task Force recommendations have consequences and can deprive patients of lifesaving services.

Last year, the GOP Doctors Caucus wrote a letter to CMS urging them to withdraw the, quote, "nonrecommended PSA-based screening," close quote, quality measure that was based on Task Force recommendations. CMS did withdraw the draft measure, but this situation clearly demonstrates the danger of the broad discretion that the USPSTF represents to patients.

Legislation, as Chairman Pitts pointed out, does provide accountability and transparency for the public. It provides

opportunities for stakeholders to give their input. I understand the value of identifying preventive services. I recognize that they can prolong the lives of Americans. I recognize they can save taxpayer dollars. However, it is important that a process is in place to ensure providers and patients that they are involved in the development of recommendations that carry so much weight and that patients and their doctor retain a share of the decision-making process.

Thank you, Mr. Chairman. I will yield back the balance of the time.

Mr. <u>Pitts.</u> The chair thanks the gentleman, and now recognize the vice chair of the full committee, Mrs. Blackburn, 5 minutes for opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman.

And I am so appreciative that we are moving forward on this legislation today. And I wish Mr. Rush were already in the room. I just want to commend him and his staff for the work that they have done on this issue. And Mr. Rush had a birthday last week and he thought having this hearing was a pretty good birthday present for him, because he does want us to move forward on this.

And our legislation will address some of the concerns that have been articulated, the growing concern over a number of the USPSTF recommendations, and the attempt to control cost by limiting patient access to preventative care. And I appreciate that the subcommittee is taking the time to drill down on the issue and that our witnesses are working with us on this.

We want to make certain that the advice and the guidance that is there is appropriate. And Mr. Burgess said it well, that patients and doctors are going to have their say in this process. Congress must not allow Federal agencies to be making the individual health choices on behalf of providers. Health decisions in the country must remain between doctors and patients.

Currently, there is no congressional appointment process or oversight mechanism within the USPSTF. Further, I am concerned that the Task Force members do not always meet with relevant stakeholders during the review process and often there is no public dialogue with medical specialists who have years of expertise on the matters that are under review.

Over the years, we have learned that this insular decision-making process at times directly conflicts with the informed views of expert physicians. The USPSTF turned its back on over 20 million women by finalizing erroneous guidelines that would limit access to mammograms for women between the ages of 40 and 50. Their recommendations have impacted PSA tests and skin cancer checks. Their reach is broad and can impact each and every one of us at any time.

Therefore, it is timely that this committee examine the Task Force to ensure transparency and accountability and make certain those are embedded in the process. Scientific evidence should motivate decisions but also support informed decision-making between physicians and patients. It is important that we reform the flawed system and ensure informed patient-centered choices are provided.

Congress does have the oversight responsibility, and today's hearing will help us to better understand the implications of recommendations and their impact on access to health care.

Mr. Chairman, I have got six statements for the record, to submit for the record. These are all in support of the bill. They are from the Men's Health Network, Solis Mammography, the National Business Group on Health, the Urology Policy Forum, and the HR Policy Association. And, with that, I yield back my time.

Mr. <u>Pitts.</u> The chair thanks the gentlelady.

Is anyone else seeking time? If not, I will add to the UC request a letter from the National Association of Pediatric Nurse Practitioners, a statement from ZERO - The End of Prostate Cancer. And the Democratic members have asked me to enter into the record a number of documents, including Ranking Member Green and Pallone's opening statements, letters to the committee from a number of parties with statements regarding the Preventive Services Task Force.

Without objection, so ordered.

[The information follows:]

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Mr. <u>Pitts.</u> All right. As usual, the opening statements of the member, written opening statements will be made a part of the record.

We will now go to our first panel. We have two panels today.

The first panel -- thank you very much for coming today -- is Kirsten Bibbins-Domingo, Ph.D., M.D., M.A.S., chairwoman of the USPSTF, the Task Force. So welcome. Your written opening statement will be made a part of the record. You will be recognized for 5 minutes for your summary. The chair recognizes the gentlelady.

STATEMENT OF KIRSTEN BIBBINS-DOMINGO, M.D., PROFESSOR OF MEDICINE AND OF EPIDEMIOLOGY AND BIOSTATISTICS, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, CHAIRPERSON, U.S. PREVENTIVE SERVICES TASK FORCE

Dr. <u>Bibbins-Domingo</u>. Thank you very much, Chairman Pitts and members of the House Energy and Commerce Health Subcommittee. I am grateful for the opportunity to talk with you today about the U.S. Preventive Services Task Force.

I am the chair of the Task Force, and I am professor of medicine and epidemiology at the University of California, San Francisco. I am also a general internist, and I provide primary care to a diverse population of adult patients at our public hospital in San Francisco, Zuckerberg San Francisco General. I have been in practice for more than 15 years.

Primary care providers specialize in preventing disease before it starts. Let me tell you a bit about a patient I saw in clinic several weeks ago. Ruth is a lovely, active 63-year-old woman. During our visit, she asked me what many of my patients do. What can I do to make sure I live a long and healthy life to lower my chance of getting sick in the future?

I take my answers to these questions very seriously. I want to be clear that the things that Ruth and I decide together have some chance of preventing disease and prolonging or improving her life. I also want to make sure I can give Ruth a complete understanding of the side effects of the tests and treatments. I want to be sure that she is more likely to benefit from my recommendations than to be harmed. She has put her trust in me, and I want to know that my advice and our shared decisionmaking will help her keep healthy for many years to come.

This is what we do in primary care. We make recommendations for people without signs or symptoms of disease about services aimed at preventing future disease and prolonging healthy life. And because of this important responsibility, it is crucial that we know what the science says.

I want to help Ruth prevent breast cancer and cervical cancer and colorectal cancer. I also want to minimize her chance of developing a heart attack or stroke, to help prevent her from falling, and to identify any underlying depression. For Ruth, and for the many patients like her, we look to the Task Force for guidelines to tell us about the range of preventive services that might be applicable and whether they are likely to be beneficial.

As background, the Task Force was established in 1984 under the Reagan administration. We are an independent nonpartisan expert panel that works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services, such as screenings, counseling, and preventive medications. All Task Force members are experts in evaluating the scientific evidence.

We value the input of subspecialists. We have explicit procedures for working with subspecialists and for getting their feedback at every stage in our recommendation process. For example,

we are now working to update our recommendation on prostate cancer screening, and we have engaged 15 subspecialty experts with expertise in prostate cancer, including urologists. We have found that engaging subspecialists on specific recommendations where they have expertise to offer is the most effective and efficient approach to our work.

I want to be clear that decisions about insurance coverage are not in our domain. These are the domains of insurers, regulators, the State, and the Federal Government. We do maintain that regardless of how health care is financed, knowing what the science tells us is critical. This was true when we were created over 30 years ago and it remains true today.

One of the joys of primary care is being able to develop a relationship with our patients over time. I look forward to continuing to get to know Ruth even better and to working in partnership with her, armed with the science, to make decisions that can help keep her healthy. As Ruth ages, we will face different decisions and we will perhaps make different choices. I know that I can look to the Task Force to help guide our conversations.

It is the trust in the Task Force's high-quality, unbiased recommendations that gives us confidence as primary care providers to answer Ruth and the many, many patients like her with assurance when they ask, what can I do to live a long and healthy life and reduce my chance of getting sick in the future?

Thank you for inviting me to testify today. I look forward to our discussion.

[The prepared statement of Dr. Bibbins-Domingo follows:]

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Mr. Pitts. The chair thanks the gentlelady.

We will now begin questioning. I will recognize myself 5 minutes for that purpose.

Dr. Bibbins-Domingo, in your testimony you mentioned the extensive process that the Task Force undertakes to produce your recommendations. Would you please elaborate a little bit more, explain the structure of your recommendations?

Dr. <u>Bibbins-Domingo</u>. Sure. We have an explicit process for and procedures that guide the way we do our work. We have an open nomination process. We publish in the Federal Register and solicit nominations from the public. When we take on a topic, we post our draft research plan for public comment, and we solicit specific comments from specialty groups and from other groups that might be concerned about specific populations. We then incorporate all of that feedback into our final research plan. That guides how we review the evidence.

When we get the evidence together, our evidence report that is conducted by the evidence-based research centers, as well as our draft recommendation statement, are posted for public comment. We take the public comment process extremely seriously and we take the process of getting comments from specific experts in the field very seriously.

We review all of those comments, and then our response to those comments and how we have changed our recommendation goes into the final recommendation, which is then issued. We do about 12 recommendations a year.

Mr. <u>Pitts.</u> Okay. Would you please explain the review process

of the comments that you receive through the recommendation process?

Dr. <u>Bibbins-Domingo</u>. Sure. So we have a Web site. Anyone can comment on the Web site. We read every single comment. And the way we address the comments, we summarize at the end of our document. We highlight all of the themes that come up in the comments. And then we also not only list the themes in the comments, but explicitly how we have addressed those themes, so that someone can see from beginning to end what we are doing in response to the comments.

Mr. <u>Pitts.</u> How do you incorporate feedback that you have received through the comment process? Do individuals who submit comments receive a response directly?

Dr. <u>Bibbins-Domingo</u>. Individuals don't receive a response directly, but all of the comments are read, and we take seriously responding to the major themes that are contained in the comments. And that is why we publish them in our final recommendation, so that you could trace our response to that particular theme.

The range of responses might be sometimes people are bringing attention to specific studies, other times people are asking us to clarify sections of our document. It is critical to us that we found all of the evidence and that we communicate clearly. And so that is how we use our comments primarily to make sure we have not missed anything in the evidence and that our statement is as clear as it can possibly be to as many people who are interested in our recommendations.

Mr. <u>Pitts.</u> Now that the Affordable Care Act ties your recommendations directly to insurance reimbursements, do you feel that

the Agency for Healthcare Research and Quality still meets the needs of the Task Force?

Dr. <u>Bibbins-Domingo</u>. The Agency for Healthcare Research and Quality has done an outstanding job. We have really expanded our efforts, in the time I have been on the Task Force, to increase our transparency, to increase our availability to the public. We have a Web site with over 10,000 hits a month. We have an app. We have many products to communicate. And the logistical support for all of that comes from the Agency for Healthcare Research and Quality.

Mr. <u>Pitts.</u> Do you believe that there should be a clearinghouse within HHS to modify the recommendations, if needed?

Dr. <u>Bibbins-Domingo</u>. I am not commenting on the specific legislation. We hope that -- we believe that the independence of our Task Force and having an independent body to evaluate science is essential. What others do after they receive our reports, I think, pertains to the other decisions that happen after that. The decisions about coverage, the decisions about other things that one might do with the recommendations, that should happen after our process. The science is what is foundational to our work, and that is what it has been since the beginning and what we continue to do.

Mr. <u>Pitts.</u> The chair thanks the gentlelady. My time is expired.

The chair recognizes the gentleman from Illinois, Mr. Shimkus,

5 minutes for questions.

Mr. Shimkus. Thank you, Mr. Chairman.

I am going to kind of go off script because I am curious on -- I

have got a couple questions just for you, Doctor. And I appreciate you coming here and I appreciate your service.

So you are an internist, right?

Dr. <u>Bibbins-Domingo</u>. Yes.

Mr. <u>Shimkus</u>. And you work for a public hospital. Tell me about the hospital.

Dr. <u>Bibbins-Domingo.</u> I work for the University of California, San Francisco. So we have many different sites. We have a VA, we have a community site, we have a public hospital site.

Mr. Shimkus. So the public hospital, you named it. What was --

Dr. <u>Bibbins-Domingo</u>. Zuckerberg San Francisco General.

Mr. <u>Shimkus</u>. And so how is that -- is that financed through San Francisco government taxes partly? I mean, the funding and compensation for health care is a big deal in this country, and so I am always curious when there are publicly funded hospitals, safety net hospitals, they come probably through property taxes or sales taxes from different entities. I know you may not know this, but --

Dr. <u>Bibbins-Domingo.</u> We actually do in part, but we also -- about half of our patients are publicly insured patients through Medi-Cal or Medicare, so that is about our distribution. And then, of course, we are part of the city government. I am paid by the University of California, San Francisco. We are also a public institution, but that is who pays my salary. And so I get money from the University of California, San Francisco. The city contracts with me to provide care there.

Mr. <u>Shimkus</u>. And then the other question is, the public hospital, there has always been a challenge of directing patients to, in essence, more urgent care type operations versus emergency operations. And that is in-house, so it doesn't matter if it is a private or not-for-profit.

Does that hospital, especially that public hospital, do they make some effort to try to do that? You know, M-Cal has a lot of that -- if someone is sick, the emergency room, they have to be seen, whether it is really an emergent -- I call it emergent -- something really, you know, life-threatening.

So that has been a challenge in health care cost, because it is a higher cost venue to go get the -- as I use -- the fishhook cut out of your hand in an emergency room versus going to an urgent care facility.

Dr. <u>Bibbins-Domingo.</u> Yeah. I would say -- you know, it is interesting. Our hospital is the city and county trauma center, but we also provide primary care. And so my patients I have seen in clinic I have seen for over 10 years, for most of them. And I would say, because all of us are professors at the University of California, San Francisco, we are committed to delivering evidence-based primary care, and so we are a combination of both of those things in our system.

Mr. <u>Shimkus</u>. But you don't know how the hospital may try to direct people from the emergency room care to an urgent care setting? You don't know how --

Dr. Bibbins-Domingo. I don't know actually how.

Mr. <u>Shimkus</u>. It is a very tactful dance of how, because probably some people view that that you can't, by the law, if people want to go. But I'm just --

Dr. <u>Bibbins-Domingo</u>. I would say, since we are the city and county's trauma center, most of those patients end up -- if other hospitals are doing that, they end up at our hospital. And I would say that as an emergency physician -- I am not an emergency physician, so I don't know how the hospital makes those decisions.

Mr. <u>Shimkus.</u> Very good. Well, I'm sorry to get off topic, but I just was very curious, based upon your testimony. Thanks for coming.

And I yield back, Mr. Chairman.

Mr. <u>Pitts.</u> The chair thanks the gentleman, now recognizes Dr. Murphy, 5 minutes for questions.

Mr. <u>Murphy</u>. Thank you.

Doctor, it is great to have you here today. So I want to ask a little bit about the prevention things. And I like the legislation that my colleague and friend, Mrs. Blackburn, is putting through here. But I want to ask you about expanding this.

So you are talking about prevention and about primary care. I want to see how we expand this and how those things fit in too. So you are familiar with the concept of primary, secondary, and tertiary prevention, right?

Dr. <u>Bibbins-Domingo.</u> Sure.

Mr. <u>Murphy</u>. So primary prevention is populationwide, to reduce or eliminate risk, et cetera; and secondary prevention are those things

that may be by genetics or family or lifestyle or environment, history, et cetera, where you minimize the risk that is already there; and tertiary, the people already have symptoms, you are going to manage what is there.

I am particularly interested in what direction you see us going into in looking at this as the integrated care of behavioral and physical health models. I am astounded when I see the Medicaid data saying that 5 percent of people are Medicaid beneficiaries, account for over 50 percent of Medicaid costs, and virtually all those have concurrent mental illness with other chronic illnesses that -- for example, people with diabetes or heart disease or lung disease. It doubles the risk of depression and other psychological disorders and, untreated, it doubles their cost.

And when I have seen studies on whether it is people with migraine headaches, they have a migraine, they go to the emergency room, they get the mega workup, MRI, CT scan, et cetera, or when they have issues too where -- inflammatory bowel disease, cancer, just pick it out, lots of visits to physicians and emergency rooms. But when that primary care physician manages the case very carefully, so it is not just integrated care but coordinated care, and then capitated care in the sense that everybody has a stake in this, doing the right thing, how that works better.

So I wonder if you could comment on how primary care and what we need to do in the areas of medicine and as we look to reform the healthcare model for delivery, the role the primary care physician has

in that and how they can integrate that behavioral medicine and physical medicine together for not just cost savings but, really, life savings.

Can you comment on some of those things?

Dr. <u>Bibbins-Domingo</u>. I think you are commenting on the very large role for primary care providers. And I think that that is an important role and one that, for those of us who were drawn to primary care as a calling, that is why we went to primary care, to take care of the whole patient, to think in an integrative way about how we can care for them.

For me and my role in the Task Force, preventive care is a big part of that. Trying to prevent disease, primary or secondary prevention, which is in the purview of the Task Force, is essential to the work that we do, and it is work that, really, there is no other specialty in medicine that is doing that. Primary care is the front line doing that.

I think the large role of primary care providers in the way we deliver care means that we have to be able to provide the tools for primary care providers to be able to do their work most effectively. And our role on the Task Force is to give them the tools for what the science tells us about prevention in a way that they can make sure that they are delivering high-quality, evidence-based care in the midst of all of the things that they are responsible for doing. And that is what we take seriously on the Task Force.

Mr. Murphy. So when you said that primary care -- and I know we do not have enough primary care providers, and you refer in your

I saw recently was where doctors working with inflammatory bowel disease, they give examples of people who have symptoms. And traditionally, it has been one where, you know, a physician can bill on a fee-for-service model and just it is a lot of cash. And they say, you know, this person, they are always calling my office, I am not going to see them.

But they actually flip that around, and the primary provider says, we are going to see you as often as you need to, and you are going to have my direct phone number and you can text me or email me at any time. And they really find that they keep those people out of emergency rooms and they get more directed care.

So this is something that you are seeing as well and how we can put -- and some of them even said, hey, the money we save, they actually have a psychologist on staff, a psychiatrist on call. They can Skype them at any time. And these people's health improve dramatically. Part of what you are looking at as well?

Dr. <u>Bibbins-Domingo</u>. Yes. So I really can't comment on how we finance health care. That is not my area of specialty or the focus of the Task Force. I can comment on the fact that we do take prevention seriously and we take seriously both mental health and physical health, just the things that you are talking about.

We have a recommendation on screening for depression. And I think that that was very important, not just the recommendation and the evidence base, but that we looked in a variety of different

populations -- pregnant and postpartum women, older adults -- to make sure that we can address the mental health needs, and then that we follow it up to make sure that it is not just screening but followup.

Mr. Murphy. Right. This is what I want to know, that as you are looking at your data, are you seeing cost savings that come? That when you screen that person with heart disease and you recognize they also have depression, when you treat those things, does it save money? Are you pulling up that data or no?

Dr. <u>Bibbins-Domingo</u>. So we aren't. The Task Force doesn't consider cost. It is not an area that is our focus. We are really focused on effectiveness. And so we are focused primarily -- but we know that it is important to identify people who have underlying depression who may not have those symptoms at the surface, because when we do that, treating that is effective for improving their health.

Mr. Murphy. Thank you. Yield back.

Mr. <u>Pitts.</u> The chair thanks the gentleman, now recognize the gentlelady from Tennessee, Mrs. Blackburn, 5 minutes for questions.

Mrs. Blackburn. Thank you, Mr. Chairman.

And, again, thank you for being here and for working with us, because we do want to move forward on this.

I want to go back into your testimony, because you mentioned the subspecialists that you had identified and used and that you value their input. So let's talk about process, and talk to me about how you identify the subspecialists that you use. The three urologists, let's take that as kind of our case study. The urologists that you identified

for the study on prostate cancer, go into how you selected them. What is your decision-making process?

Dr. <u>Bibbins-Domingo</u>. Yes. So I have to say that I don't know all of the specifics of the process for identifying them. I will say it is important to us that we evaluate a few things. One is our process takes a fair amount of commitment to do, so it takes a period of time. So commitment to the entire process. We vet the conflicts of interest very seriously, and so that is an important feature in how we look at this. And we want people who are going to be experts in this area. That is probably fundamental. We are looking for people who have expertise in screening and treating prostate cancer who can help advise us for every stage.

I don't exactly know how. I do know, and I learned in the process here, that our chair of urology at the University of California, San Francisco is one of the experts that is consulting with us. He is an outstanding physician. But I would have to defer to -- and I hopefully can get the information back to you --

Mrs. Blackburn. Yes, that would be --

Dr. <u>Bibbins-Domingo.</u> -- on exactly how we choose them.

Mrs. <u>Blackburn.</u> That would be great. If you would submit to us what that process is.

Dr. Bibbins-Domingo. Sure.

Mrs. <u>Blackburn.</u> How you all go about it. I think it would be helpful to us.

And let me ask you this. Did you seek input from the AUA? Did

you go to any of these groups and seek their input and say, do you have people to recommend? Or did you go to the clinical oncology, go to the American Society of Clinical Oncology and say, do you have people that you want to recommend to us?

Dr. <u>Bibbins-Domingo.</u> So, again, I don't want to be off in my comments on the very specifics here on prostate cancer. I would say we routinely engage with the specialty societies that have expertise in the topics. The American Cancer Society I know, because we do several cancer topics, is one where we do that.

And so we engage very specifically and deliberately, not just to help us identify experts, but also to help give us feedback on each of our steps in our process.

Mrs. <u>Blackburn.</u> Okay. And you mentioned you were surprised to learn that one of your colleagues was serving on the prostate task force. So what is the transparency modeling for making the information public of who is serving on these task forces?

Dr. <u>Bibbins-Domingo</u>. Yeah. I guess that is publicly available. My surprise just reflects that I have not looked at every single expert for every single topic. I was pleasantly surprised, and I think it reflects not just that I am recommending our friends but, rather, that there is an independent process to really find the experts who really have expertise in this area and who can devote the time to really giving us feedback throughout the process. So it just reflects that we do many topics, as I said, and I don't know the list in all the topics so --

Mrs. <u>Blackburn.</u> You mentioned that you all do not consider cost. Dr. Bibbins-Domingo. That is right.

Mrs. <u>Blackburn.</u> So are you concerned that the Task Force recommendations affect coverage?

Dr. <u>Bibbins-Domingo</u>. It was the decision of Congress to link the Task Force recommendations to coverage. We existed before that linkage. And regardless of how health care is financed, the science of what works, how do we know what works is essential. We think that is essential to how doctors and patients make their decisions together. And we know that people use that information in these other venues, but our processes have not changed. They have been the same before the ACA, they have been the same after the linkage was made. And, really, it is our process and our evaluation of science that is foundational. It is other people's jobs to determine the coverage.

The other thing I would say is that oftentimes Congress has expanded the coverage. They have decided what is supposed to be covered. That is exactly what we think should happen. That is not our domain. And so the example in breast cancer, where we said women from 40 to 74 benefit from screening, 40 to 74 we have given a grade that there is benefit from regular mammography screening, the decision of Congress was to cover all of those women. And that is somebody else's decision. In my view as a clinician, it is the appropriate decision. And that is what we think the process should be. We don't do coverage. We do the science, and other people should determine the coverage.

Mrs. <u>Blackburn.</u> Do you think that limiting coverage is linked to your decisions that it is used as a measure to control cost? Do you think that is inappropriate?

Dr. <u>Bibbins-Domingo.</u> Again, we don't consider cost. We don't do coverage. Our processes are really for evaluating the science.

Mrs. <u>Blackburn.</u> But would you call it inappropriate that limited access many times gets linked to your decisions?

Dr. <u>Bibbins-Domingo.</u> So I would say, as a clinician, I am always concerned that patients have access. As a clinician, I understand the value of access.

Mrs. <u>Blackburn</u>. So that would be of concern to you?

Dr. <u>Bibbins-Domingo</u>. I think that those people who determine coverage and access should act to assure that there is access for patients who need it. I would like for the science to help inform, but the decisions about coverage have always been made by other people, and science is only one of the pieces that should play into a coverage decision. We think it is a piece, an important piece, but it is only one of the decisions.

Mrs. <u>Blackburn.</u> Excellent. I yield back.

Mr. <u>Pitts.</u> The chair thanks the gentlelady, now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. Lance. Thank you very much, Mr. Chairman.

And good morning to you, Doctor, and thank you for being with us.

In your testimony, you mentioned the 2012 prostate cancer screening recommendation. And I am interested to know -- as I

understand it, only 4 percent of the clinical trial participants were African Americans. And we all know that African American men have an extremely high rate of prostate cancer. And I would like your views on that and how we might improve the process moving forward.

Dr. <u>Bibbins-Domingo</u>. This is such an important issue, I am really happy that you brought this to light. As you say, African Americans suffer from prostate cancer at higher rates and, unfortunately, they are included in our clinical trials and the evidence base at much lower numbers.

Our process means we have to use the evidence to arrive at our recommendations. When we don't have the evidence, we don't substitute our judgment and what we might do in clinical practice with a particular patient. We can't substitute that. What we do do is we make specific language in our recommendation statements to highlight important evidence gaps, and we hope that this will prompt the scientific community to then engage in the process of doing the scientific studies that we need to generate the guidelines.

This is what we did in 2012 with prostate cancer. We highlighted the fact that it is really a sad reality that we have so few African American men included in the trials. We called for more studies on African Americans and other high-risk men. That is very important for our evidence base. We also gave clinicians some tools. We said, we know that you are going to continue screening some people, and if you do that, we think you, doctors and patients together, should understand benefits, should understand harms, and make informed decisions when

making the decisions about screening, because we know that doctors still need to act without evidence and we try to give some guidance for doctors and patients to do that.

Mr. <u>Lance</u>. Thank you, Doctor. Are there other minority groups where the numbers are not as high as they should be, based upon percentages in the population?

Dr. <u>Bibbins-Domingo</u>. In prostate cancer, it sticks out in particular. In other recommendations, we have focused on other groups. For our diabetes and obesity recommendation, we have focused on Asian Americans and Pacific Islanders. For every group we have tried to focus on where the evidence gap is because, especially if that group is disproportionately affected by a disease, we need the evidence in order to figure out whether we should be doing something different.

Mr. <u>Lance</u>. Is there a disproportionate effect regarding certain minority groups related to diabetes, for example?

Dr. <u>Bibbins-Domingo</u>. I think that with diabetes -- diabetes occurs at a lower body weight in Asian Americans, and I think that is what we wanted to highlight there. It is occurring at high rates, but it is at a lower body weight, so sometimes physicians may not know. That is what it says explicitly in our recommendations. It is important for doctors and patients to know that a person from an Asian background who might be not obese by our current thresholds might still have a risk for diabetes.

Mr. <u>Lance</u>. Thank you. And in another area, how do morbidity and mortality rates factor into the current scientific review analysis and

reporting on public health matters?

Dr. <u>Bibbins-Domingo</u>. Great. So we look at the rates of morbidity and mortality for a condition. That is important background information for all of our recommendations. If there is a group, a group by age or by race, ethnicity, or by parts of the country, or something that is disproportionately affected, we highlight that and we try to understand whether we need to tailor a recommendation in some way.

Sometimes we don't have enough information to do that, but we provide all of the information about morbidity and mortality rates in our recommendation statement, so that the doctor who is sitting in their own clinic can make the decision for the patient in front of them. We want to give them all the tools, and we write much more than just the top line grade so that a doctor faced with a patient in front of them can make their own decisions.

Mr. <u>Lance</u>. Thank you very much for your expertise.

And I yield back half a minute, Mr. Chairman.

Mr. <u>Pitts.</u> The chair thanks the gentleman, now recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions.

Mr. Bucshon. Thank you, Mr. Chairman.

Good to see you and thank you for being here. As you know, the house of medicine changes slowly. I was a physician before I was in Congress, a surgeon. That said, the level of skepticism, I think, that you are probably hearing from the committee is based on the fact that the ACA links what you do to coverage. And the ACA happens and suddenly

recommendations are less testing in certain areas. And so that, unfortunately, has brought suspicion on your hard work and all the really quality work that you do. Because there is interest from governments, whether that is the United States or others, as well as private payers in what your recommendations are and how that may or may not save them money. So that is the lead-in to my questions.

The biggest question I have is, kind of describe how you choose studies that you might include because, as you know, in medicine there are literally tens of thousands of clinical studies that come out from around the world, many of which they are paid for by different entities, whether that is government, whether that is private, and also some that are non-U.S. studies that could call into question whether or not that is applicable to the American people.

So can you kind of describe how you might figure out, for example, on just any issue how you pick and choose what studies to look at?

Dr. <u>Bibbins-Domingo.</u> Sure. Thank you. So the evidence-based practice centers that are located at universities around the country, they conduct the evidence review after we give them the research plan that we agree on.

They are going to comb through all of the evidence, but they are going to focus primarily and use the studies that are done in the U.S. That is going to be a particular focus. And they are going to be particularly concerned about who is funding the studies, because we know that the people, the entities that fund studies, they can perhaps dictate or lead to bias in those studies.

So a best study for us would be a study that is done in the U.S., that is not funded by industry, that would be funded by the NIH. That would be probably our highest quality study, and then, depending on the study design, would be most likely to inform our particular decision. We rate the quality of a study, and the quality of the study includes who is funding it and how relevant it is to our population.

Mr. <u>Bucshon</u>. Yeah. Thank you for that. Because some of the mammogram recommendations came based on some Canadian data, I think.

So I want to give you the opportunity on some of the more controversial areas, prostate screening and mammograms, to maybe clarify what your recommendations actually said, including some details that might help us on the committee get a better idea of what they actually said versus what sometimes the impression that is created what they have said.

Dr. <u>Bibbins-Domingo.</u> Great. So thank you for the opportunity to do that.

So for breast cancer, I want to be clear. We recommended that there is evidence -- we said, there is evidence that mammography works for women between the ages of 40 and 74. That is what we said. It works -- there is a greatly likelihood of benefit in older women than younger women, but we did say that many women will choose to screen in their forties, because the evidence says that it works in the forties, even though the likelihood of benefit is smaller. It is often miscommunicated that we said women shouldn't get screened in the forties. That is absolutely untrue. It is not what we said.

In prostate cancer, there is a mixed bag of evidence. There is evidence of benefits. There is also evidence of important harms. We said that on balance, that we didn't think there should be routine screening in everyone. We did say, if you are going to engage in screening, you should make an informed decision and know the benefits and the harms.

I want to speak to the issue that you raise that, since the Affordable Care Act, we have made decisions that appear to take away something.

Mr. <u>Bucshon.</u> I just said the appearance of. I didn't say that you had.

Dr. <u>Bibbins-Domingo</u>. I want to highlight that many things -- many things have actually -- because we now have more evidence, we now have more confidence to recommend actually more things. We have a recommendation for use of statins to prevent heart disease. We have a recommendation to screen for lung cancer with CT scans. We have recommendations to screen for diabetes and to screen for depression. All of those things that we moved from insufficient evidence to now a B grade evidence, because scientists have done the work, we now have the evidence and we can make that recommendation.

Mr. <u>Bucshon</u>. Okay. Thank you very much.

Dr. <u>Bibbins-Domingo</u>. Not at all.

Mr. <u>Bucshon</u>. I yield back.

Mr. <u>Pitts.</u> The chair thanks the gentleman, recognizes the vice chair of the committee, Mr. Guthrie, 5 minutes for questions.

Mr. Guthrie. Thanks a lot.

And just, actually, Dr. Bucshon asked a couple questions I was going to ask, but just kind of piggybacking a little, what do you say -- as you said, the appearance. You know, things happen, things change in Washington, D.C., then you start hearing recommendations that, as you have described today, is not really accurate that you said don't screen, have mammograms when you are 40, wait till later. I mean, that is the kind of stuff that you hear and so you just tie together. That is why these hearings are important to flesh this out.

And so just looking at transparency, I guess, within your group. So one of mine was the Task Force -- I understand that you guys have actually, the Task Force has taken steps over the past years to improve transparency. Do you agree that more can be done? And then how would you recommend that if the information you put out isn't accurate, because it certainly was portrayed in the public that way, how would you kind of recommend that that information flows better?

Dr. <u>Bibbins-Domingo</u>. So I would say transparency is core, it is a core principle to the work that we do. If people don't trust our recommendations, it is not good for us, because we want people to use our recommendations. So I would say our efforts over time have been to improve what others see and hear about us. That is why we have worked to talk with as many groups that we can who might have an interest in a particular population or a particular disease about what the Task Force does. We urge them to read beyond our top-line recommendation to understand all of the text that we have written, and to help them

use the text how they might use it in clinical practice or in other settings.

We have worked on our Web site and other tools for dissemination, other tools to make it easier for doctors and patients to make the decisions together, because they have other tools available to them.

I think an important feature of our work is that the integrity, our conflicts of interest process, and the integrity of the Task Force, I think, is essential for allowing many more groups to feel that they can come to the Task Force and their recommendations and see something they might be able to use. And I think it has helped us in our dissemination. But, of course, we always want to work to improve.

Mr. <u>Guthrie</u>. Thank you. And what Dr. Bucshon asked, I was going to ask you, is how you determine your research plan, how you determine how you are going to move forward. If you are in a research plan and you are looking -- and say you see something that has been brought up that, well, we only have 4 percent African American men, we know that there are different effects of these kind of studies, that they would be more susceptible to prostate cancer; therefore, let's change our plan to -- I mean, how do you react to those kind of things within the research plan? I mean, do you just put an asterisk to say, this doesn't really reflect this group of people? I mean, that is pretty serious when you screen or don't screen, based on your makeup. Yeah.

Dr. <u>Bibbins-Domingo.</u> It is a really great question. I had this discussion most recently with an advocacy group for African American men with prostate cancer. They gave a summit here on Capitol Hill on

African American prostate cancer disparities, this group, Prostate Health Education Network, PHEN. They provided us comments on our research plan. We posted the draft. We included a lot of information about African American men that we hope to be a focus.

They provided us comments that made it clear that we should include different types of studies. And so based on their comments, we actually expanded our research plan directly in response to their comments. And I was really happy to see, when I went to this particular summit, that they commented that they could see the changes in our research plan.

I will say in the end, when there are no studies, that is itself a limitation, because we cannot not make guidelines on no evidence.

Mr. Guthrie. Right.

Dr. <u>Bibbins-Domingo</u>. So we have to call for more research when there is no research. But we always provide language that hopefully helps doctors and patients make decisions even in the absence. And so the fact that African Americans are disproportionately affected, they have higher rates, those are the types of things we include in our recommendations so that doctors and patients might make that decision, even in the absence of evidence saying that the screening is effective.

Mr. <u>Guthrie</u>. Well, thanks for that. And the discussion draft we are looking at today requires collaboration between other agencies. And I believe collaboration is key, it must be done to connect all health agencies. How often does your group, your Task Force work with NIH,

DOD, CMS, or the VA?

Dr. <u>Bibbins-Domingo.</u> Oh, we are really fortunate to have very strong partners. And the National Cancer Institute is one of our strongest. They come to all of our meetings. They give their input on what science might be in progress that they have funded. And they take very seriously when we say we are stuck here because we don't have enough evidence in this area. That helps inform how they might prioritize certain types of research within their agency.

We also have -- the DOD is present there. I can't remember all of our partners, but our partners are present at our meeting, and that has been essential to us, both for providing input to us but also for helping to disseminate, to get the words out to their own communities, and to informing other research.

Mr. <u>Guthrie.</u> Well, thank you, and I appreciate your answers. And I yield back.

Dr. <u>Bibbins-Domingo.</u> Thank you.

Mr. <u>Pitts.</u> The chair thanks the gentleman, and now recognizes the gentleman from New York, Mr. Collins, 5 minutes for questions.

Mr. <u>Collins.</u> Thank you, Mr. Chairman.

Thank you, Doctor, for coming in. I think you have answered a lot of our concerns, but I guess I would just like to reiterate on the specialist piece. We do hear from some of our urologists and others on the specialty care piece that the Task Force is primarily made up of the, you know, primary care type physicians, but as you have moved into making some recommendations in the specialty areas.

I think you have answered a lot of those concerns here, but just to follow on just to make sure that is always top of mind that, you know, these folks are concerned. They are worried. You can understand why.

Dr. <u>Bibbins-Domingo</u>. Absolutely.

Mr. <u>Collins</u>. But to follow up on something Representative Blackburn asked you about, the cost piece, I think you said you don't factor in cost. But if I could just read something to you, and I just looked up the current law on the Task Force, and it says directly, "The Task Force is directed to review the scientific evidence related to the effectiveness, appropriateness and cost-effectiveness of clinical preventive services." So really, that is in your charter to take into account the cost-effectiveness, yet -- you know, is there a disconnect here where you said you don't take into account cost?

Dr. <u>Bibbins-Domingo</u>. You are right that it is in our charter. We have never in our 32 years considered cost. It is explicitly on our Web site. It is our policy not to consider cost. And the main reason is we want people to focus on effectiveness. We want people to understand what works and not to get confused that we might be rationing or trying to withhold something or trying to shift in any other way. We made our own decision not to consider cost, because we have left it to other people to make that determination related to coverage.

But you are right, it is in our charter, but we have never done it in the 32 years we have been in existence.

Mr. <u>Collins</u>. Shouldn't you change your charter then or ask us to -- I mean, there is always the issue. It is there for a reason and you are just ignoring it. I mean, it is not supposed to work that way.

Dr. <u>Bibbins-Domingo</u>. It is a good question. I personally think that -- and I think that the rationale behind the Task Force making the decision not to consider cost is because people get worried that we are withholding things or making decisions because of cost. We want to start first with what works. And by not considering cost, we can focus on what works.

Mr. <u>Collins</u>. Well, just a recommendation. You know, if that is on there, you should perhaps put a disclaimer that says, even though we were directed to do this, we have, in our own judgment, decided to ignore that and here's our reason. I mean, I know why you might not want to do that.

Dr. Bibbins-Domingo. Yes.

Mr. <u>Collins</u>. It might make people not realize you are doing that. But transparency is transparency.

Dr. Bibbins-Domingo. Yes.

Mr. <u>Collins.</u> So you have answered the question. Question asked, question answered. I would say I think you owe it to put something like that up there or change the charter or get us to change it. I mean, you realize you are kind of operating in the smoke-and-mirror world.

Dr. <u>Bibbins-Domingo.</u> Actually, Congressman, I believe it is on our Web site.

Mr. Collins. Okay.

Dr. <u>Bibbins-Domingo</u>. I appreciate that we might be able to make it more widely -- make more aware that that is the case, but I do believe it is on our Web site that we don't consider cost.

Mr. <u>Collins</u>. You have answered the question and I brought it up, and thank you for that.

And with that, Mr. Chairman, I will yield back.

Mr. Pitts. The chair thanks the gentleman.

That concludes the questions of the members who are here. We will have followup questions. I am sure other members will have questions. We will send those to you, ask that you please respond.

Dr. <u>Bibbins-Domingo</u>. Okay.

[The information follows:]

****** COMMITTEE INSERT ******

Mr. Pitts. With that, thank you very much, Doctor.

And we will call our second panel to the witness stand. And there are two members, and I will introduce them in the order of their presentations. First, Dr. John Lynch, member of the American Urological Association, chairman, professor, Department of Urology of Georgetown University; and secondly, Dr. John Meigs, M.D., F.A.A.F.P., president of the American Academy of Family Physicians.

Thank you very much for coming today. Your written statements will be made a part of the record. You will each be recognized for 5 minutes to summarize your testimony.

So I would like to first recognize Dr. Lynch for 5 minutes.

STATEMENTS OF JOHN H. LYNCH, M.D., CHAIRMAN AND PROFESSOR, DEPARTMENT OF UROLOGY, GEORGETOWN UNIVERSITY; AND JOHN MEIGS, JR., M.D., PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

STATEMENT OF JOHN H. LYNCH, M.D.

Dr. Lynch. Chairman Pitts, Ranking Member Green, members of the Energy and Commerce Health Subcommittee, and honored guests, my name is Dr. John Lynch, and I am testifying today as a member of the American Urological Association, and as a practicing urologist, prostate cancer researcher, and professor and chairman of the Department of Urology at MedStar Georgetown University Hospital.

Mr. <u>Pitts.</u> Just pull it closer to you a little bit. Yeah, thank you.

Dr. Lynch. I also appear before you today as a prostate cancer survivor, who feared that if the U.S. Preventive Task Force recommendations were in existence when I was diagnosed, my prostate cancer might have been missed. Early detection saved my life, which is why this hearing today is of utmost importance.

The AUA would like to thank the subcommittee for taking an in-depth look at H.R. 1151, the USPSTF Transparency and Accountability Act. This legislation, spearheaded by Representatives Marsha Blackburn and Bobby Rush, would make four key reforms to enhance the transparency and accountability of the Task Force. First, it would

ensure that representation of the Task Force is balanced, to include practicing specialty care providers. Second, the bill requires an accountable and transparent process for comments and considerations related to research plans and recommendations. Third, the bill would establish an advisory board to ensure regular input from interested stakeholders and Federal agencies and payers likely to be impacted by Task Force recommendations. Fourth and finally, it would require a process to request review of previous recommendations when additional peer-reviewed scientific evidence is available.

These reforms are necessary because the Affordable Care Act requires coverage without copayment, coinsurance or deductible when provided by an in-network provider for certain age-appropriate preventative health services. Those services include Task Force recommendations with grade A or B. This change in law shifted the role of the Task Force from a scientific advisory body to a body with the authority to influence Federal benefit and coverage requirements.

However, the long-term impacts of these recommendations aren't always clear. For many patients, the stakes are high. Earlier this year, the Task Force published a final research plan to update the PSA screening recommendation. That is a good thing and something urologists and many patients have been urging for for the past several years. However, since the release of the 2012 recommendation, providers face conflicting recommendations and patients did not know how to determine what was best for their individual needs.

More accountability and transparency in the Task Force process

would help identify evidence that should be reviewed and identify any potential issues earlier in the process. Likewise, it would be helpful for the Task Force to acknowledge other recommendations or practice guidelines available in the medical and patient community as well as those issued by Federal agencies.

The recommendations clearly have an impact on patient care. Last year, the Journal of the American Medical Association published two peer-reviewed studies which documented that fewer men are being screened for prostate cancer and fewer early-stage cases are being diagnosed and detected. These studies highlight that the cases have not dropped because the disease is becoming less common but because there is less effort to find it.

Because prostate cancer often grows slowly, the Task Force said, screening finds many tumors that may have never harmed the patient, resulting in potential overtreatment for some patients.

RPTR KERR

EDTR ZAMORA

[12:00 p.m.]

Dr. <u>Lynch.</u> As a result, it concluded, testing saves few lives and leads too many men into unneeded surgery or radiation, which potentially leaves them impotent and incontinent.

I and many other urologists strongly disagree with the Task Force's assessment. Rather than issuing a blanket recommendation that ends screening, it would be better to screen smarter. These decisions are best made between the physician and the patient, taking into consideration their individual risk factors and family history.

The AUA's 2013 guideline emphasizes the importance of shared decisionmaking as well as a consideration of risk factors.

Representation by urology or other medical specialties is noticeably absent from the Task Force. By including, in some manner, those that treat conditions for which recommendations are being made, the Task Force will ensure appropriate interpretation of currently available literature and can benefit from added expertise and input into the diagnosis and treatment of a disease or condition, as well as ensure the appropriateness and relevance of recommendations in a clinical setting.

I understand that every specialty provider cannot be represented full time on the Task Force, but having a specialty voice for individual recommendations can improve the outreach and review process.

Likewise, an advisory board would allow more formal and consistent input and improved engagement of interested stakeholders.

I hope that Congress will enact USPSTF Transparency and Accountability Act to improve the process for determining preventive care coverage and access for patients. I am happy to answer any questions or follow up with any additional information.

Thank you, Mr. Chair.

[The prepared statement of Dr. Lynch follows:]

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Mr. Pitts. The chair thanks the gentleman.

Now recognizes Dr. Meigs, 5 minutes for your summary.

STATEMENT OF JOHN MEIGS, JR., M.D.

Dr. <u>Meigs.</u> Chairman Pitts, Ranking Member Green, and members of the Health Subcommittee, thank you for the opportunity --

Mr. Pitts. Can you poke the button? Yeah. That's it.

Dr. <u>Meigs.</u> -- to testify on behalf of the American Academy of Family Physicians and our 125,000 members. I am honored to serve as AAFP president, and I proudly represent physicians who, like myself, provide essential primary care services and rely on the integrity of the U.S. Preventive Services Task Force. It is important to note that the cornerstone of optimal health depends on a robust primary care and preventive health system.

Decades of studies confirm that States with a higher concentration of primary care physicians have better health outcomes, including lower rates of all-cause mortality, even after controlling for socioeconomic, demographic, and lifestyle factors. Research also shows that the benefits of primary care are measurable. An increase of one primary care physician for 10,000 people is associated with an average mortality reduction of 5.3 percent. In real terms, in real lives, that represents 49 fewer deaths per 100,000 of the population per year.

In addition, high quality primary care is necessary to achieve

the triple aim of better patient care, improve population health at lower cost. Evidence-based Task Force recommendations help family physicians frame discussions with patients who are at risk for disease, guiding them to make informed decisions based upon timely scientific information and their personal preferences.

For example, when the Task Force made its 2009 decision about mammography screenings for women aged 40 to 49, my patients had questions. We discussed what the recommendations meant for them as individuals, considering their health status, family history, and personal preferences. My patients came to different decisions. Some wanted to screen anyway, others declined.

Currently, four family physicians serve on the Task Force, and the AAFP has its own experts who also review the evidence and Task Force recommendation statements that we adopt and share with our members. Overall, the AAFP has come to rely on the Task Force's objective rigorous assessment of scientific medical evidence. The AAFP believes the current composition of the Task Force is appropriate and should not change. Thus, enactment of H.R. 1151, in our opinion, would undermine the Task Force.

First, H.R. 1151 calls for specialty representation on the Task Force. Subspecialists already contribute to the Task Force process, and their expertise is consulted every step along the way, and the final vote is left to those with expertise in primary care and evidence-based preventive medicine.

While we respect our specialty and subspecialty colleagues, their

role in treating specific conditions and organ systems is not the same as developing guidelines to screen for and prevent such conditions.

Second, the legislation would require input from the broader healthcare industry. In recent years, Task Force members and even our AAFP liaisons have been subjected to intense lobbying from professional societies as well as pharmaceutical and medical device companies that have significant economic interest in its recommendations. I have no doubt that pressure from these groups would only increase if H.R. 1151 were to be signed into law, and consequently, family physicians would be unable to trust that the Task Force's recommendations were completely unbiased.

Third, the legislation would require the Task Force to assess how its decisions or grades would impact access to health services, devices, Federal programs, or private health insurance coverage. The AAFP strongly supports the current process and function of the Task Force and believes that its recommendations should be independent of cost and access considerations.

In conclusion, I want to call your attention to two key principles. The first is an underlying tenet in all of medicine: Primum non nocere, first, do no harm.

The second principle, which is not unique to medicine but certainly seems apropos to today's discussion is if it ain't broke, don't fix it.

Ladies and gentlemen, the U.S. Preventive Services Task Force is not broken. It does important good work on behalf of primary care

physicians and our patients. I urge you to maintain this valuable source of unbiased evidence-based primary care guidance. Please, do no harm.

Again, I thank you for inviting me to testify, and I would be happy to answer any questions you might have for me.

[The prepared statement of Dr. Meigs follows:]

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Mr. <u>Pitts.</u> The chair thanks the gentleman, and we will now begin questioning. I recognize myself 5 minutes for that purpose.

Dr. Meigs, in your testimony, you mention the importance of the doctor-patient relationship. I agree with that. How do we ensure the Task Force recommendations still value this relationship with the insurance tie to the Task Force recommendations?

Dr. Meigs. The Task Force recommendations apply to the population, and it is a difficult concept to understand when you are talking about the population as a whole or an individual. It still is important, when I have my patient in my exam room, that she and I or he and I discuss the risk and benefits, the harms, cost, and concerns about whatever treatment may be under discussion.

So we use the Task Force recommendations as a starting point as the basis for a discussion, but that is a recommendation based on what is best for the population. That does not change the individual decision that I make with my patient one-on-one.

Mr. <u>Pitts.</u> All right. Dr. Lynch, as you know, the Task Force was formed in 1984. What do you think the true impact of the Task Force has been? Is there a way to measure their influence on the health of our Nation within the physician communities?

Dr. Lynch. Well, I can address that specifically to prostate cancer, which I am far more familiar with and can tell you that there is now evidence in the literature, following the 2012 recommendations, and I have personal experience with this as well, that we are seeing a larger percentage of men with metastatic prostate cancer and higher

rate and higher stage prostate cancer than we did before these recommendations. So I would say that that has had a deleterious effect on the health of these men.

Mr. <u>Pitts.</u> As a urologist, would you please speak to the specific importance of regular PSA test? Why do you think the Task Force did not recommend routine PSA tests in 2012?

Dr. Lynch. I know the Task Force has excellent intent. They base their recommendation on 2012 primarily based on two studies. One was called the PLCO study, which is in the United States, and the other was the European trial. The PLCO study is flawed in that actually a report of the New England Journal of Medicine last year described how there were actually a higher percentage of men in the arm that was not supposed to be screened who actually received screening than the men in the screened arm. So there is really no differences in those two arms, and one would not expect to show a mortality difference. So I don't think the literature was there to really support the recommendations.

Mr. <u>Pitts.</u> So how do you think the Task Force can prevent something like this from happening in the future?

Dr. <u>Lynch</u>. By involving specialists who treat the disease. I understand, as I said in my testimony, that not every specialist can be present on the Task Force, but I think a specialist has a different skill set, and a lot of them are experts in evidence-based medicine who would actually add to the Task Force. And I certainly think the importance of the advisory board comes through with that when you can

have specialists in open dialogue, just like this is an open hearing, you can have an open dialogue between an advisory board and the Task Force to try and look at these issues and discuss these issues in person.

Mr. <u>Pitts.</u> How often do you think the Task Force should review recommendations they have previously issued?

Dr. Lynch. I think that depends on the literature, and there should be access to be able to do that. I think, for example, if they make a recommendation today, and there is evidence in the literature next year to support a different recommendation, they should be able to review that and change that. Waiting 5 years is too long.

Mr. <u>Pitts.</u> Would you please elaborate on your views of the grading system the USPSTF uses for recommendations? Do you believe the discussion draft addresses your concerns?

Dr. Lynch. The grading systems are A, B, C, and D. Right now, a patient's coverage is tied to A and B. I think that the draft legislation would help to improve that system by giving more input, again, to the Task Force and providing more evidence from specialists.

Mr. <u>Pitts.</u> In your testimony you mention the disconnect between practicing physicians and the Task Force. Would you elaborate on that a little bit?

Dr. Lynch. I can elaborate. If you look at the makeup of the Task Force, for example, there are primary care physicians, there are internists, there is geriatricians, there is pediatricians, there is obstetrics and gynecology. There is no one representing men's issues. Men's health is certainly an important issue.

Urologists -- interestingly enough, in this area, there is a fair number of my patients who don't have a primary care physician and don't have an internist. So even yesterday I had to screen for -- talk about tobacco sensation, talk about weight reduction for an obese patient, alcoholism, depression, in addition to their prostate cancer. So I think adding an additional person to deal with that would also be very beneficial.

Mr. <u>Pitts.</u> Do you believe the discussion draft before us today would solve some of this disconnect?

Dr. Lynch. Yes, I do.

Mr. Pitts. Thank you. My time is expired.

The chair recognizes the vice chair of the full committee, Mrs. Blackburn, 5 minutes for questions.

Mrs. <u>Blackburn.</u> And I will not take all of my 5 minutes. I do want to thank you all for being here.

And, Dr. Lynch, let's go back to your testimony. The AUA guidelines differ from the USPSTF guidelines. So I want you just to walk us through a patient who comes to you and needs that care, and what does the impact and the difference of those guidelines have on the care that that patient has access to?

And I appreciate what you just said about timely review. I think that technology, advances in technology, utilization of informatics and delivery of health care is something that changes so rapidly. We never keep pace with that. Government doesn't keep pace with that. So I think the differences in these guidelines, how often you all change

yours, what you see or what hesitancy you see from the Task Force, if you will just speak to that and that relevance to the patient.

Dr. <u>Lynch.</u> Congressman Blackburn, thank you for the question.

If I can give you a specific example --

Mrs. <u>Blackburn</u>. I would love it, yes.

Dr. <u>Lynch</u>. -- related to a patient. About 8 weeks ago, I had a African American gentleman walk into my office in his mid-50s with some urologic symptoms. After a day or two of testing, I had to sit down with this gentleman and tell him that he had metastatic prostate cancer that had spread throughout his skeleton, that he was treatable but certainly not curable.

I went back and reviewed his records. He had been receiving, at high risk as an African American male, PSA testing up through 2012, and then his internist or primary care physician stopped getting the PSA. He did not have evidence of prostate cancer in 2012. Now he has widely metastatic prostate cancer. That was a difficult discussion.

He asked me why, why didn't he do this, why didn't they get this test? It's a very difficult situation to deal with, and unfortunately, we are seeing it more and more.

Mrs. <u>Blackburn.</u> Okay. Thank you.

And with that, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentlelady.

I now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. Murphy. Thank you, Mr. Chairman.

I don't know if you heard some of the questioning I had for the previous presenter, but I want to raise some of those for you as well, and then looking at the integrated care model and noting how, when we are looking at behavioral and physical medicine together and managing them in terms of primary, secondary, and tertiary prevention, whether it makes a difference in terms of quality of care.

Obviously, the patient you just mentioned must have been dealing with a great deal of psychological issues at that moment of describing it, and we know a person can be overwhelmed with anxiety, with panic, with depression, deterioration of family, other stresses that can come with a diagnosis or even a risk of a problem. And I have seen studies where people have actually looked at this, having the primary care physician work with the specialist and very carefully managing the psychological and the physical medicine aspects, and they improve compliance or they reduce errors, medication compliance, et cetera.

I am wondering if, in your work, you have also looked at those aspects as well and what you have found in looking at those parts of prevention and cost savings and better care.

Dr. Lynch. Well, I think that is key, and I think, again, as the urologist delves into a lot more of men's health and their urologic issues, a conversation back with their internist or primary care physician. Because sometimes they will bring things up to me, as the urologist, that they won't necessarily bring up to their primary care physician. So the dialogue back from the specialist to the primary care is getting -- the key to getting that patient the care that he

needs and wants and that, in the long term, is going to reduce costs.

Mr. <u>Murphy</u>. Do you also then, with that, do screening, or do you recommend the primary care physician also do some screening for other things like depression, anxiety, and the impact that may have upon their illness?

Dr. Lynch. Absolutely. And we do that as urologists, especially in dealing with cancer patients. That is a very frequent occurrence, and that is something we have to watch very closely for.

Mr. <u>Murphy.</u> Dr. Meigs, do you do work in this area, too, in that same -- look into behavioral, physical medicine aspects?

Dr. Meigs. In primary care and family medicine, we see behavioral and psychological problems every day all day long. That is an extremely important part of our practice, and there is no way for a good primary care physician to divorce mental health and behavioral health from physical or other sources of health care. I mean, we treat people. We don't treat organ systems or diseases. We treat the whole person. And if you ignore that subset of problems, you have not adequately treated the individual.

So we are especially in tune to looking for the depressed patient, the anxious patients, patient with other mental health issues that need to be addressed because they most definitely have an effect on their physical health.

Mr. <u>Murphy</u>. So we have -- in testimony we have heard before this committee in other parts of Energy and Commerce, we recognize a person who has a severe mental illness, for example, 75 percent of the cases

have at least one other chronic illness, 50 percent have at least two, a third have at least three, and that also the person with severe mental illness has triple the risk for poverty, and the person in poverty has triple the risk for severe psychological disorder. I mean, the list goes on and on as you have these.

And that we have heard that some practice which actually employ people to work in behavioral medicine, social worker, psychologist, or have telemedicine with a psychiatrist there, they can address those things immediately as opposed to saying, here is a card, call this person, and let us know what happens. Because when it is just a referral, compliance drops below 50 percent. When it is in the office, a warm handoff, it is high level.

So in the practice of primary care and family medicine, is that something that you are able to do or do you see that, look, that is not billable hours right now, and so we can't do that but even though there is a need?

Dr. Meigs. There is a shortage of primary care physicians. There is just as much a shortage of mental health workers, psychiatrists, and psychologists. I would love to have one in my office. I could use them every day.

I practice in a rural community of 2,700 in central Alabama. There are no mental health professionals. That is a big area of concern for me and my patients. When I have patients whose needs exceed my abilities, trying to find someone to see them or somewhere they can get to, then you get into the other social determinants of health, they

can't afford the transportation, they have no one to take them, they have all the other issues that become involved when we are trying to meet a real critical need for these people.

Mr. <u>Murphy</u>. So that you know, we are going to have a bill before the House in a couple of hours here to vote on, such things as providing telemental health consultation for primary care, and I hope that is something that we can get into nationwide to really help the rural areas. Over half the counties in America, as I said before, have no psychologist, psychiatrist, social worker to deal with these things, but we know it is a pervasive problem throughout the field of medicine that is hurting patients.

We want to hear more from you in the future of how we can do this with secondary and tertiary prevention and help reduce the problems.

Thank you very much.

I yield back.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions.

Mr. <u>Bucshon</u>. First of all, thank you both for being here to testify today.

And, Dr. Meigs, I respectfully disagree that a specialist might not have more input. I mean, as both of you know, this is a classic house of medicine battle that starts in the first year of medical school between -- in primary care providers and specialists, and it is seen here today again, unfortunately. But it is what it is. We all work

together. We all know we have a specific role in taking care of the patients.

But in this particular instance, just when we are looking at studies and input to try to decide what the appropriate screening is, what is the down -- what would be the downside of having more specialist input, other than, from my -- as a specialist, other than as a -- like I said, a battle between in the house of medicine that begins literally in the first year of medical school? I mean, what would be the potential downside?

Dr. Meigs. You know, I certainly would hope that -- and I am sure our urology colleagues are more than competent to take care of the urological diseases, but the U.S. Preventive Services Task Force, their job is to look at the evidence and make recommendations for primary care on screening for primary prevention of diseases.

It is a different concept. And as we have already testified, they bring in the consults, they bring in the consultants, they bring in the specialists to evaluate the evidence. But these are physicians and others who are specialists in primary care, in preventive care, in evaluating evidence, and making recommendations on the quality of the evidence as to an unbiased recommendation I can use every day in the exam room with my patient about what is best for them.

Mr. <u>Bucshon</u>. Yeah. I mean, do you think from -- I mean, I was -- I saw a lot of patients with tertiary care disease and heart disease primarily, right, or lung cancer. And, you know, I have -- I found in my own practice that, you know, working together with my

primary care referring doctors, that that kind of collegial discussion about what my treatment options were of their patient for this particular thing, whether or not I have an area of expertise, which I don't claim to have in primary prevention, it just seems to me that there is not really a downside to at least having specialists involved in discussing, you know, what the potential treatment options are and what the potential downsides are of changes in screening recommendations. Because as Dr. Lynch has pointed out, it does affect specialists if you change the screening recommendations for prostate cancer or breast cancer or other things.

To get that, you know, at least followup input maybe later on, like we are getting from the 2012 recommendation, say, hey, look here is the result, primary -- how would primary care physicians know that that is the result until their patient comes back to them, I guess, with problems that were not -- you know, that were recognized at a later state? I mean, that is all I am saying.

I mean, I just think that the more input you get in healthcare -- I found that to be true as a heart surgeon, all right, I mean, I was one -- you know, if I had an infectious problem, I would call an ID person. I mean, I didn't claim to be -- I mean, I got as many -- many minds thinking about a problem as I could get on behalf of the patient.

So I am just trying to get why there is a potential downside in having more input on this. I just -- as a specialist, I am having a hard time seeing that.

Dr. Meigs. As you well know, a lot of the diseases that you

treated and that we all treat are preventable.

Mr. <u>Bucshon</u>. They are, yeah.

Dr. <u>Meigs.</u> For me, it is a success if I can get my -- if my patient needs you when he is 85 instead of when he is 45 because I treated his blood pressure --

Mr. Bucshon. I agree.

Dr. <u>Meigs.</u> -- I treated his cholesterol, I got him to exercise, I got him to lose weight and eat better, then I think that has been a success. You have a much more dramatic outcome, but I think the value to the society is just as good for what I do in that case.

Mr. <u>Bucshon</u>. Absolutely. You are getting no disagreement from me. In fact, in the last seconds I have, I want to address the nationwide shortage of primary care physicians, and we are trying to figure out why that is. And we have to address that issue in our country.

Southern Indiana, rural Indiana where I live, we have a critical shortage in our rural counties of primary care physicians. And to your point, without that success that you have for your patients, the patients end up seeing me or Dr. Lynch at a later stage.

So it is critically important. We are adding a medical school branch of Indiana University Medical School in Evansville, Indiana, more residency programs. And so as a Member of Congress, I am doing what I can to get that message out, that whatever we can do to increase primary care, we should be doing.

Dr. Meigs. For preventive care and primary care, when I send a

patient to you, I have got a failure.

Mr. Bucshon. I understand.

I yield back.

Mr. Pitts. The chair thanks the gentleman.

That concludes questions of members present. As always --

Mrs. Blackburn. Mr. Chairman --

Mr. Pitts. Yes.

Mrs. Blackburn. May I reclaim a moment of my time just to make --

Mr. Pitts. All right. Go ahead.

Mrs. <u>Blackburn</u>. -- one clarification for the record. Going back to what Mr. Collins had said, going to the USPSTF Web site, I think we do want to note that under the standards for guidelines and development, in that section, they absolutely do not list that they don't consider cost or they don't note that they do not follow their charter. And when you go to a screen shot and -- or you go to your Web page, and this is a screen shot of it, and enter the word "cost," nothing comes up. So we may want to just consider that as we look at changes for the Task Force.

I yield back.

Mr. <u>Pitts.</u> The chair thanks the gentlelady for her clarification.

We will have followup questions, other members have questions, we will send those to you. We ask that you please respond. I remind members that they have 10 business days to submit questions for the record. Members should submit their questions by the close of business

on Wednesday, December 14.

So thank you very much for coming, for your expertise, for sharing in a very important hearing.

Without objection, this hearing is adjourned.

[The information follows:]

****** COMMITTEE INSERT ******

[Whereupon, at 12:26 p.m., the subcommittee was adjourned.]